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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

FOREMAN, JONATHAN M

ART UNIT

PAPER NUMBER

3736

MAIL DATE

DELIVERY MODE

04/06/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/615,510	Applicant(s) KLINT, HENRIK S.	
	Examiner JONATHAN ML FOREMAN	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 March 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 13-30 and 32-36 is/are pending in the application.
- 4a) Of the above claim(s) 2, 7, 8, 10, 11, 13-18, 20, 21, 23-28 and 32-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-6, 9, 19, 22, 29 and 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 3736

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/23/10 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1, 3 - 6, 9, 19, 22, 29 and 30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1 and 19 include the limitations related to a distal end portion having a substantially constant second diameter along a distance of ***at least four wound coils***. Figure 29 appears to provide support for a constant second diameter along a distance of four wound coils. However, ***at least four wound coils*** is open ended and includes more than four coils. As such, there is no support in the specification as originally filed for the open ended limitation of ***at least four wound coils***.

Art Unit: 3736

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1, 3 - 5, 9, 19, 22, 29 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,748,986 to Morrison et al. in view of U.S. Patent No. 5,993,424 to Lorenzo et al.

In regard to claims 1, 3 - 5, 9, 19, 22, 29 and 30, Morrison et al. disclose a body portion (Figure 4) having a first diameter and comprising a multiple filament group of individual wire coils wound adjacent to one another (Col. 3, lines 27 – 30; Col. 4, lines 36 – 41), defining an open lumen (Figure 4); a distal end portion having a substantially constant second diameter along a distance of at least four wound wire coils (Figure 4), wherein the second diameter that is less than the first diameter; a taper portion having a taper from the first diameter to the second diameter; and a coating disposed over the distal end portion, taper portion, and at least a part of the body portion (Col. 3, lines 8 – 10). The coating comprises an elastic low-friction coating (Col. 3, lines 8 – 10) that defines a taper adjacent the taper portion in that the coating is applied to the taper portion.

Morrison et al. disclose an open lumen, the open lumen including a core wire. Morrison et al. fail to disclose the open lumen being unoccupied for substantially its entire length. Lorenzo et al. disclose a guidewire having an open lumen (Figure 2). Lorenzo et al. disclose the open lumen having a core wire which is movable in the open lumen to enable the open lumen to be occupied or unoccupied for substantially its entire length (Abstract). It would have been obvious to one having ordinary skill

Art Unit: 3736

in the art at the time the invention was made to modify the core wire as disclosed by Morrison et al. to be moveable as taught by Lorenzo et al., thus allowing the open lumen to be unoccupied for substantially its entire length, in order to allow the guidewire to assume different configurations (Abstract).

6. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,748,986 to Morrison et al. in view of U.S. Patent No. 5,993,424 to Lorenzo et al. as applied above and further in view of U.S. Patent No. 5,980,471 to Jafari.

In regard to claim 6, Morrison et al. in view of Lorenzo et al. disclose the guidewire having a coating comprising a low-friction coating such as Teflon (Col. 3, lines 8 – 10), but fail to disclose the coating being a hydrophilic material. Jafari disclose a guidewire having a low-friction coating including Teflon or a hydrophilic material (Col. 6, lines 37 – 42). It would have been obvious to one having ordinary skill in the art at the time the invention was made to replace the Teflon coating disclosed by Morrison et al. in view of Lorenzo et al. with the hydrophilic material as taught by Jafari in that Jafari teach a Teflon coating and a coating including hydrophilic material as being functionally equivalent and therefore interchangeable. Additionally, the claim would have been obvious because the substitution of one known element for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Because both Morrison et al. and Jafari teach low-friction coatings for use on a guidewire, it would have been obvious to one skilled in the art at the time of the invention to substitute one coating for the other to achieve the predictable results of reducing drag on the guidewire during insertion into a body.

7. Claims 1, 4, 5, 9, 19 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,178,158 to de Toledo in view of U.S. Patent No. 5,993,424 to Lorenzo et al.

Art Unit: 3736

In regard to claims 1, 4, 5, 9, 19 and 22, Morrison et al. teach a guidewire (Abstract) including a proximal body portion (11) having a first diameter and comprising a multiple filament group of individual wire coils wound adjacent one another (Col. 4, lines 42 – 45), defining an open lumen (22); a distal end portion (13) having a substantially constant diameter along a distance of at least four wound wire coils, and an elastic low-friction coating (40) disposed over the distal end portion and at least a part of the proximal body portion. De Toledo discloses the distal portion having a flexibility greater than the proximal portion (Col. 4, lines 54 - 57). However, de Toledo fails to disclose the proximal portion having a first diameter and the distal portion having a second diameter less than the first, and a taper portion having a taper from the first diameter to the second diameter. Lorenzo et al. teach a medical device (Figure 2) having a proximal portion (42) having a first diameter, a distal portion (44) having a second diameter smaller than the first diameter over a distance of at least four wound wire coils (Figure 2) and a tapered portion (Between 42 and 44) having a taper from the first diameter to the second diameter. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the guidewire as disclosed by de Toledo to include a tapered portion between the proximal portion and a distal portion having a reduced diameter so that the tip of the guidewire can accommodate a radiopaque marker band if desired (Col. 3, lines 25 - 28). Creating a tapered portion would result in the multiple-filament group of wire coils forming the taper being wound at a pitch angle different than a pitch angle of a multiple-filament group of individual wire coils of a body portion in that the diameter from which the coil is round is reduced.

Response to Arguments

8. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection. Applicant states that although pitch angle may be used in

Art Unit: 3736

conjunction with tapering, neither automatically necessitates the other. However, if coil spacing remains constant when the diameter of a hollow tubular changes, then the pitch angle must change as well.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JONATHAN ML FOREMAN whose telephone number is (571)272-4724. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. M. F./
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736